IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit	: 1645	**Customer No.: 035811**
Examiner	: JaNa A. Hines	
Serial No.	: 10/795,873	
Filed	: March 8, 2004	
Inventors	: Jean-Pierre Hermet	Docket No.: 1049-04
	: Isabelle Besson-Faure	
	: Sébastien Ribault	Confirmation No.: 3189
	: Yann Godfrin	
	: Anne Monnot des Angles	
Title	: DEVICE AND METHOD FOR	
	: CONCENTRATING AND DETECTING	
	: PATHOGENIC MICROBES FROM BLOOD	
	: PRODUCTS AND/OR THEIR DERIVATIVES	
		Dated: May 19, 2009

RESPONSE

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is submitted in response to the Official Action dated February 17, 2009.

The Applicants note with appreciation the withdrawal of the prior rejections.

Claims 1-5, 8, 10, 14-17, 23-28 and 37-38 now stand rejected under 35 USC §103 over the hypothetical combination of Aunet and Zierdt with Doshi. The Applicants note with appreciation the Examiner's detailed comments hypothetically applying the combination against the above-mentioned claims. The Applicants nonetheless respectfully submit that even if one skilled in the art were to make the hypothetical combination, the method resulting from that combination would still be quite different from the Applicants' claimed method as recited in the above claims. Reasons are set forth below.

The rejection frankly acknowledges that the primary reference, Doshi, does not teach the method being performed in an enclosed and sterile device and comprising selectively lysing the cells in recovering microbes with a second filter having a pore size of about 0.3 μm to less than 1 μm which retains contaminating microbes and allows passage of cellular debris. The Applicants agree. The rejection thus turns to Aunet for the teachings of a device comprising an enclosed

and sterile housing. The rejection specifically points to columns 5 and 6, lines 67-3 and Figs. 1 and 2 as recited at the bottom of page 6 of the Official Action.

The Applicants respectfully submit that, while Aunet discloses a housing and entry and exit ports, there is no disclosure that the device is "enclosed and sterile" as recited in the rejection and as claimed in the Applicants' Claim 1, for example. The Applicants first invite the Examiner's attention to the above-mentioned text spanning columns 5 and 6. A slightly broader excerpt of that text is reproduced below for the Examiner's convenience.

> FIGS. 1-2 are depictions of exemplary devices used to separate plasma from whole blood according to the first embodiment of the present invention As illustrated in FIG. 1, an apparatus (**10**) comprises a housing (**12**) which has an entry port (**13**) and an exit vent (**16**). Located within the housing (**12**) is a device (**17**) comprising a porous polyethylene matrix (**18**) which contains an agglutinating agent and is molded into a cylindrical shape having the dimensions of 3.5 mm in diameter and 5 mm in height.

This disclosure in Aunet does not mention that the device is enclosed and it does not mention that it is sterile. Moreover, there is no suggestion that it could be or should be enclosed.

Also, there are other portions of the Aunet text that mention the housing or the inlet or the entry port, but do not suggest that structure is closed and/or sterile. For example, column 5 at lines 46-49 recites:

> According to one method of utilizing the first preferred embodiment of the device of the present invention, a sample of whole blood is applied to an inlet or first end of the matrix.

There is no mention of the sample being introduced into a closed or sterile device. Then, in column 6 beginning at line 19, there is further discussion with respect to Fig. 2. That discussion beginning at line 19 recites:

> As illustrated in FIG. 2, an apparatus (**30**) comprises a housing (**32**) which has an entry port (**33**) and an exit vent (**36**).

Again, there is no mention of this structure being enclosed and no mention of it being sterile.

The Applicants then invite the Examiner's attention to the front page of Aunet which contains Fig. 1. The Applicants have added an arrow A to the entry port (13) area and an arrow B directed to the outlet port (16) area. The Applicants enclose a copy of the marked-up Aunet Fig. 1 for demonstration purposes. It can be seen that the polyethylene matrix (14) is completely

open on its upper surface to the ambient atmosphere. That portion of the matrix (14) is not enclosed and, being open to the ambient atmosphere, is inherently not sterile. Similarly, the matrix (20) is also not enclosed. The rightmost face of that matrix (20) is open to the ambient atmosphere through exit port (16) and is therefore not enclosed and inherently not sterile.

The other figure mentioned in the rejection, namely Fig. 2, is similarly constructed wherein the upper surface of the matrix (38) is exposed in the ambient atmosphere as is the rightmost surface of the matrix (42) in Fig. 2. Thus, both the inlets and outlets are not enclosed and not sterile.

The Applicants have examined the entirety of the Aunet disclosure and respectfully submit that there is no mention of the device being enclosed and no mention of the device being sterile. In that regard, the Applicants invite the Examiner's attention to Example 1 which employs a device that is shown in Fig. 2. As noted above, that figure provides for inlets and outlets that are exposed to the ambient atmosphere thereby inherently making them not enclosed and not sterile. Example 1 includes an actual application of the device shown in Fig. 2 and there is nothing in that description that indicates that the device was enclosed and/or sterile.

Example 2 refers to the device shown in Fig. 3. Again, there is nothing that suggests that the matrices in the device are enclosed and/or sterile.

Example 3 uses the same device as shown in Fig. 3 as already discussed and there is no indication that the device are enclosed and/or sterile.

Example 4 uses the device of Fig. 1. This disclosure is slightly different in that it appears, but does not explicitly disclose, that the exit port is attached to a device capable of generating a vacuum. For the sake of argument, if it is assumed that attaching such a vacuum-pulling device to the exit port would be considered an enclosure, it would still lead the inlet port open to the ambient atmosphere. However, there is no mention of the vacuum-pulling device being sterile.

None of the remaining examples provides any additional different disclosure that indicates that the entry or exit ports are enclosed and/or sterile.

What does this mean? If one skilled in the art were to hypothetically combine Aunet (and Zierdt) with Doshi, the result of that combination would be a method wherein the device of Aunet is used in conjunction with the methodology of Doshi (and Zierdt). However, taking the teachings of Aunet and applying them to Doshi would still not result in a method/device that

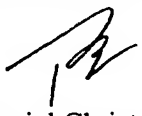
employs an enclosed and sterile device. The Aunet device is disclosed as being open to the ambient atmosphere and there is simply no disclosure of whether the device is sterile. Moreover, there is nothing in Aunet that leads one skilled in the art to conclude that the device should be enclosed and/or should be sterile. Thus, that combination results in a method that uses a device that is open to the atmosphere and there is no teaching concerning whether there are sterile conditions or not. As such, the Applicants respectfully submit that that combination still does not result in the subject matter of the Applicants' Claims 1-5, 8, 10, 14-17, 23-28 and 37-38. Withdrawal of the rejection is respectfully requested.

Claims 6 and 7 stand rejected under 35 USC §103 over the further hypothetical combination of Cathey with Doshi and Zierdt. The Applicants respectfully submit that the combined disclosure of Doshi and Zierdt as admitted in the earlier rejection cannot and does not result in the Applicants' subject matter as recited in Claims 1-5, 8, 10, 14-17, 23-28 and 37-38. The Applicants respectfully submit that Cathey fails to provide additional disclosure, teachings or suggestions that would cure the deficiencies set forth above with respect to the Doshi/Zierdt combination. In other words, there would still be no disclosure that the device is enclosed and sterile. Withdrawal of the rejection is respectfully requested.

Claims 9 and 13 stand rejected under 35 USC §103 over the further hypothetical combination of Besson-Faure with Zierdt, Aunet and Doshi. The Applicants respectfully submit that Besson-Faure fails to cure the deficiency set forth above with respect to the Zierdt/Aunet/Doshi combination. Withdrawal of that rejection is also respectfully requested.

In light of the foregoing, the Applicants respectfully submit that the entire application is now in condition for allowance, which is respectfully requested.

Respectfully submitted,



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